

April 01, 2005

Office of Nutritional Products
Labeling & Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Notification of Dietary Supplement Statements

Dear Sir or Madam:

This letter is to notify you that Garden of Life, Inc. wishes to use a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act in a product label and/or labeling.

## Manufacturer/Packer/Distributor Name and Address:

Garden of Life, Inc. 5500 N. Village Blvd. Suite 202 West Palm Beach, FL 33407

Brand Name: Garden of Life

Product Name:  $\Omega$ -Zyme<sup>TM</sup>

## Statement(s):

- Malt diastase (maltase) digests maltose based carbohydrates or malt found in grains
- Papain, derived from papaya, also digests proteins into peptides and amino acids
- Pectinase breaks down carbohydrates such as pectin, found in the pulp of many fruits
- Phytase breaks down phytic acid present in many difficult-to-digest grains and beans. Research supports the view that phytic acid present in plant foods interferes with digestion of proteins and utilization of many important minerals, such as Zinc, Magnesium and Iron
- Lipase digests fats
- Provides 20 different digestive enzymes that help you process proteins, carbohydrates, fats and difficult-to-digest foods like broccoli, nuts, seeds and beans
- Cellulase digests fiber cellulose into smaller units
- With 20 different digestive enzymes, Ω-Zyme provides a broad array of enzymes to help your body process a wide variety of foods.
- Protease blend of five proteolytic enzymes aids digestion and utilization of dietary proteins
- Lactase digests the milk sugar lactose
- Invertase (sucrase) is an enzyme that breaks down sucrose into glucose and fructose

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• Hemicellulase breaks down carbohydrates widely present in plant foods

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• Consuming enzyme rich foods and/or highly active enzyme supplements like  $\Omega$ -Zyme are two valuable approaches to ensure your body gets the enzymes it needs to support healthy digestion - which is essential to overall health.

- Bromelain, derived from pineapple, breaks down a broad variety of proteins
- Beta-glucanase breaks down bulky beta-glucan molecules into smaller units
- · Amylase digests starch
- Alpha-galactosidase helps digestion of difficult-to-digest foods such as beans, legumes and cruciferous vegetables
- Xylanase breaks down xylose, also called wood sugar
- Glucoamylase breaks down starch-like carbohydrates

I hereby certify that the information contained in this notice is complete and accurate, and that Garden of Life, Inc. has substantiation that the statement(s) indicated above are truthful and not misleading.

Dr. Leonid Ber

Title: Director, Medical Research

If you have any questions, please contact Dr. Leonid Ber, Director, Medical Research at 561-748-2477.